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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/905,041	07/13/2001	Marc Madou	22727/04096	2217

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EXAMINER	
CHUNDURU, SURYAPRABHA	
ART UNIT	**PAPER NUMBER**
1637	8

DATE MAILED: 11/20/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/905,041	MADOU ET AL.	
	Examiner	Art Unit	
	Suryaprabha Chunduru	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 November 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15 and 38-51* is/are pending in the application.

4a) Of the above claim(s) *3-5,15 and 38-40* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14 and 41-51* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Applicant's election without traverse of claims 1-14 and 41 of Group I in Paper No. 7 is acknowledged. Applicants' election of a species (biopolymer comprising proteins and polypeptides) in Paper No. 7 is acknowledged.

2. Claims 3-5 are dependent on non-elected species, hence are not considered for examination. Claims 1-2, 6-14 and 41 are considered for examination in this office action.

3. Claims 16-37 are canceled. Non-elected claims 15, 40 are withdrawn from consideration. New claims 42-51 are considered for examination along with the claims in Group I.

4. The disclosure is objected because of the following informalities:

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code (see on page 2 of the specification). Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2,6-14 and 41, 43, 45, 47-51 are rejected under 35 U.S.C. 102(b) as being anticipated by Giese (USPN. 4,478,914).

The instant claims are rejected based on broadly claimed claim 1 under the scope that any monomeric unit(s) is possible to be included in the synthetic multimeric biopolymer .

Giese teaches a synthetic multimeric biopolymer comprising monomeric units of proteins (avidin), wherein Giese teaches that the multimeric biopolymer comprises (i) monomeric units of proteins linked to each other (see column 1, lines 59-66); (ii) binding region(s) for an analyte (biotin) (see column 1, lines 59-66, column 2, lines 9-28); (iii) said multimeric biopolymer changes its three-dimensional conformation upon binding to said binding region (see column 3, lines 36-65); and at least one of the said monomeric units transmits a detectable signal (see column 5, lines 22-55, column 4, lines 40-43). Further, Giese discloses that the synthetic multimer product comprises plurality of monomeric units comprising multiple binding regions (see column 3, lines 30-38); a change in conformation of said monomeric unit could be detectable by formation of hydroxides with the incorporated label horse radish peroxidase, upon binding of an analyte and transmit detectable signal (color absorbance) (see column 5, lines 22-55); detectable signal comprises optical signal (see column 5, lines 22-55); each of the monomeric units comprises binding region and amplifies the signal generated by each monomeric unit upon binding to an analyte (see column 5, lines 30-55); and polymer comprises 2-10 monomeric units (see column 5, lines 45-55) and the monomeric units of the multimeric biopolymer were chemically cross linked to each other either covalently (reversible) or noncolvalently (see column 5, lines 1-30). Thus the disclosure of Giese meets the limitations in the instant claims.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 42, 44, and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Giese (USPN. 4,478,914) in view of Houghten (USPN. 4,886,663).

Giese teaches a synthetic multimeric biopolymer comprising monomeric units of proteins (avidin), wherein Giese teaches that the multimeric biopolymer comprises (i) monomeric units of proteins linked to each other (see column 1, lines 59-66); (ii) binding region(s) for an analyte (biotin) (see column 1, lines 59-66, column 2, lines 9-28); (iii) said multimeric biopolymer changes its three-dimensional conformation upon binding to said binding region (see column 3, lines 36-65); and at least one of the said monomeric units transmits a detectable signal (see column 5, lines 22-55, column 4, lines 40-43). Further, Giese discloses that the synthetic multimeric product comprises plurality of monomeric units comprising multiple binding regions (see column 3, lines 30-38); a change in conformation of said monomeric unit could be detectable by formation of hydroxides with the incorporated label horse radish peroxidase, upon binding of an analyte and transmit detectable signal (color absorbance) (see column 5, lines 22-55); detectable signal comprises optical signal (see column 5, lines 22-55); each of the

monomeric units comprises binding region and amplifies the signal generated by each monomeric unit upon binding to an analyte (see column 5, lines 30-55); and polymer comprises 2-10 monomeric units (see column 5, lines 45-55) and the monomeric units of the multimeric biopolymer were chemically cross linked to each other either covalently (reversible) or noncolvalently (see column 5, lines 1-30). However, Giese did not specifically teach linking monomeric units with peptide bond.

Houghten teaches a synthetic multimeric polypeptides pf a heat-stable endotoxin of E.coli, wherein Houghten teaches that the multimeric form comprises linking of monomeric units of polypeptides with peptide bonds (see column 5, lines 45-57, column 13, lines 42-68, column 14, lines 1-68).

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art at the time the multimeric polypetides comprising peptide bonds as taught by Houghten to achieve expected advantage of developing a multimeric bioplomer resembling a natural polypeptide because Houghten suggests that "biological activity and antigenicity can be obtained by using synthetic polypeptides containing at least one intramolecular, intrapolypeptide cystine disulfide bond" (see column 19, lines 39-49). An ordinary practitioner would have been motivated to combine the multimeric biopolymer of Giese with the multimeric polypeptides comprising peptide bonds as taught by Houghten to improve the synthetic multimeric biopolymer structure by linking the monomeric untis with peptide bonds for the expected advantage of developing a multimeric polypeptide to mimic the natural polypeptide with correct orientation and folding to contain desired partial biological activity.

Conclusion

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 703-305-1004. The examiner can normally be reached on 8.30A.M. - 4.30P.M, Mon - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 703-308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and - for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Suryaprabha Chunduru
November 15, 2002

JEFFREY FREDMAN
PRIMARY EXAMINER